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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/931,157	08/16/2001	Hiroo Imura	299002032411	2951

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MORRISON & FOERSTER LLP
755 PAGE MILL RD
PALO ALTO, CA 94304-1018

EXAMINER

NICHOLS, CHRISTOPHER J

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 10/17/2002

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/931,157

Applicant(s)

IMURA ET AL.

Examiner

Christopher Nichols, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 September 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 23-39 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 23 and 24, drawn to an isolated human endothelin receptor comprising SEQ ID NO: 1, classified in class 514, subclass 2, for example.
 - II. Claim 31, drawn to a pharmaceutical composition, classification dependent upon agent structure.
 - III. Claims 25-27, drawn to a method for identifying an agonist or an antagonist of a human endothelin receptor, classification dependent upon how binding is measured.
 - IV. Claims 28-30, drawn to a method of manufacturing a pharmaceutical composition, classification dependent upon agent structure.
 - V. Claims 32-34, drawn to a method for modulating an endothelin receptor, classification dependent upon agent structure.
 - VI. Claims 35-37, drawn to a method of treating a condition characterized by abnormal activity of endothelin receptors in a subject, classification dependent upon agent structure.
 - VII. Claims 38 and 39, drawn to a method of determining ET-1 or ET-2 in a sample, classification dependent upon how binding is measured.
2. The inventions are distinct, each from the other because of the following reasons:

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3. Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive Inventions that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: Inventions III, IV, V, VI, and VII are directed to methods that are distinct both physically and functionally, and are not required one for the other. Invention III requires search and consideration of identifying an agonist or an antagonist of a human endothelin receptor, which is not required by any of the other Inventions. Invention IV requires search and consideration of manufacturing a pharmaceutical composition, which is not required by any of the other Inventions. Invention V requires search and consideration of modulating an endothelin receptor, which is not required by any of the other Inventions. Invention VI requires search and consideration of treating a condition characterized by abnormal activity of endothelin receptors in a subject, which is not required by any of the other Inventions. Invention VII requires search and consideration of determining ET-1 or ET-2 in a sample, which is not required by any of the other Inventions. Each method requires a separate search of the literature and databases. A search and examination of an Invention as it pertains to all methods would therefore present the examiner with an undue search burden.

4. Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different products, restriction is deemed to be proper because these products constitute patentably distinct inventions for the following reasons. Inventions I and II are directed to products that are distinct both physically and functionally, are not required one for the other, and are therefore patentably distinct. The isolated human endothelin receptor of Invention I is independent and distinct from the product of

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Invention II because it is not required to make the isolated human endothelin receptor of

Invention I. The pharmaceutical composition of Invention II is independent and distinct from the product of Invention I because it is not required to make the pharmaceutical composition of Invention I.

5. Inventions II and IV are related as product and process of making. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be made by another and materially different process. The pharmaceutical composition of Invention II could be isolated from its natural source.

6. Inventions I and each of III, IV, V, VI, and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Inventions I and each of III, IV, V, VI, and VII are unrelated product and methods, wherein each is not required, one for another. For example, the claimed methods of Inventions III, IV, V, VI, and VII do not recite the use or production of the isolated human endothelin receptor of Invention I.

7. Inventions II and each of III, V, VI, and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Inventions II and each of III, V, VI, and VII are unrelated product and methods, wherein each is not required, one for another. For example, the

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claimed methods of Inventions III, V, VI, and VII do not recite the use or production of the pharmaceutical composition of Invention II.

8. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

9. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, separate search requirements, and/or different classification, restriction for examination purposes as indicated is proper.

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher Nichols, Ph.D. whose telephone number is 703-305-3955. The examiner can normally be reached on Monday through Friday, 8:30AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, Ph.D. can be reached on 703-308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications. The fax phone numbers for the customer service center is 703-872-9305.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

CJN

October 16, 2002



ELIZABETH KEMMERER
PRIMARY EXAMINER